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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,459	11/21/2001	Mariko Egawa	TOS-125-USA-D	2290

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EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,459

Applicant(s)

EGAWA ET AL.

Examiner

Alysia Berman

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/147,293.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1617

DETAILED ACTION

1. Receipt is acknowledged of the preliminary amendment filed November 21, 2001. Claims 5-12 and 17-19 have been canceled. Claims 1-4 and ~~13~~-16 are pending.

AB
5/21/02

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

AB
5/21/02
3. Claims 1-~~4~~ and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The claims are vague and indefinite because it is unclear if Applicant intends for the compounds listed in the Markush group at lines 9-13 of claims 1 and 13 to be the metabolic intermediates or the sulphur containing amino acids. The metes and bounds of the claims cannot be determined because it is unclear what is encompassed by the metabolic intermediates of sulphur containing amino acids.

5. The claims are vague and indefinite because it is unclear to what the Markush group at lines 17-21 of claims 1 and 13 pertains.

6. Claims 2 and 14 are indefinite because it is unclear if Applicant intends to require both of glutathione and either thiotaurine or hypotaurine. The metes and bounds of the claims cannot be determined.

7. Claims 2 and 14 are indefinite because it is unclear how thiotaurine and hypotaurine relate to the metabolic intermediates of claims 1 and 13. Neither thiotaurine nor hypotaurine are recited in claims 1 or 13.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. For prior art purposes claims 2 and 14 are interpreted as meaning that when a sulfur containing amino acid is present it must be glutathione and when a metabolic intermediate of a sulfur containing amino acid is present it must be either thiotaurine or hypotaurine. The claims do not require both glutathione and either thiotaurine or hypotaurine.

10. Claims 1, 2, 13 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Egawa et al., Cigarette smoke induced lipid peroxidation and its oxidative effect on the skin, 3rd ASCS Conference, Taipei, Taiwan, (1997), pages 217-276.

Egawa et al. teaches that cigarette smoke causes lipid peroxidation and increased the intensity of ultraweak chemiluminescence in the skin and that application of antioxidants prevented these problems (abstract). For glutathione, hypotaurine and thiotaurine as suitable antioxidants, see page 272, section 2-3-2. For application of compositions comprising a 1% solution of antioxidant, see page 278, section 2-3-3. Egawa et al. Teaches application of a composition containing 1% of an antioxidant such

Art Unit: 1617

as thiotaurine, hypotaurine or glutathione to the skin for preventing oxidation damage due to exposure to cigarette smoke.

11. Claims 1, 2, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,601,806 (806).

US '806 discloses compositions for topical use that contain antioxidants such as thiotaurine (aminothiosulfonic acid). See column 1, lines 13-20, column 3, lines 43-50, column 4, lines 60-63 and example 1 at column 12, which contains 1.0 wt.% thiotaurine. For application to the skin see the claims.

12. Claims 1-4 and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,747,049 (049).

US '049 is directed to cosmetic compositions containing an aminoethyl compound for topical application to treat and prevent cutaneous aging (abstract, column 1, lines 4-6 and the claims). For thiotaurine see column 3, lines 3-5 and the examples. For a composition containing 0.5 wt.% thiotaurine and 0.05 wt.% citric acid see Formulation Example 1 bridging columns 14 and 15.

13. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

14. The claims are directed to a method of applying a composition containing thiotaurine to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

Art Unit: 1617

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently treat environmental stress as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1617

17. Claims 1-~~14~~ and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 5,747,049 (049) or US 5,601,806 (806) each in view of Egawa et al.

US '806 and US '049 teach all the limitations of the claims as stated in the 35 U.S.C. 102 rejections above. Neither reference teaches treating environmental stress due to tobacco smoke by suppressing a reduction in corneum moisture content or suppressing ultraweak chemiluminescence from the skin.

Egawa et al. Teaches that skin damage caused by exposure to cigarette smoke can be prevented by topical application of compositions containing antioxidants such as thiotaaurine, hypotaaurine and glutathione.

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the compositions of either US '806 or US '049 each alone to the skin expecting to prevent damage caused by exposure to cigarette smoke as taught by Egawa et al.

Unexpected Results

18. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548

Art Unit: 1617

(CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).


In the instant case, no data was seen.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
May 21, 2002


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